

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of the effectiveness of two compounds Propofol - Sodium thiopental and Propofol - Etomidate on the quality of sedation and hemodynamic changes in Cataract surgery

#### Protocol summary

##### Study aim

The effect of Propofol-Thiopental and Propofol-Etomidate combination on sedation and hemodynamic status of the patient in cataract surgery

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 64 patients. Lottery and sealed envelopes are used for randomization.

##### Settings and conduct

This is a randomized double-blind clinical trial that will be performed on 64 patients undergoing cataract surgery at Feyz Hospital in Isfahan; After the approval of the university ethics committee and obtaining the patients' consent, the patients entered the groups by random allocation. In each group, the desired intervention is applied and the patient's clinical symptoms are recorded. They do not know the type of intervention. Patients, despite being studied, are not aware of the type of intervention and are therefore all blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 60 years old, Candidate for Cataract Surgery, Class I and II ASA Anesthesia  
Exclusion criteria: heart disease, mental illness, obesity, diabetes, drug allergies and addiction

##### Intervention groups

Intervention group A: In this group, patients receive 1 mg per kg of body weight of Propofol-Thiopental sodium for anesthesia. Intervention group B: In this group, patients receive 0.3 mg per kg of body weight of Propofol-Etomidate for anesthesia.

##### Main outcome variables

The amount of patient sedation during the operation; The rate of hemodynamic changes in the patient

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160307026950N37**

Registration date: **2021-10-16, 1400/07/24**

Registration timing: **prospective**

Last update: **2021-10-16, 1400/07/24**

Update count: **0**

##### Registration date

2021-10-16, 1400/07/24

##### Registrant information

##### Name

Behzad Nazemroaya

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3212 3543

##### Email address

behzad\_nazem@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-23, 1400/08/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effectiveness of two compounds Propofol - Sodium thiopental and Propofol - Etomidate on the quality of sedation and hemodynamic changes in Cataract surgery

### Public title

Effectiveness of two compounds Propofol - Sodium thiopental and Propofol - Etomidate in Cataract surgery

### Purpose

Diagnostic

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients 18 to 60 years Grade I, II and III in ASA criteria (American Society of Anesthesia) Candidate for Cataract surgery

#### Exclusion criteria:

Patients with obstructive sleep apnea, mental disorder, autoimmune diseases, diabetes, nystagmus, leukemia, epilepsy and patients treated with psychiatric drugs  
Deafness Allergy to the drugs used Use of painkillers in the past week BMI (Body Mass Index) more than 35

### Age

From **18 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **64**

### Randomization (investigator's opinion)

Randomized

### Randomization description

This is a simple randomized clinical trial in which individuals enter study groups by lottery; The drugs are placed in the desired number in sealed opaque and uniformly sealed bags. Each of the codes is also written on a piece of paper, folded and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box. Which is applied to the patient. This continues until the end of the paperwork so that the number of patients in the desired volume in the groups.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This is a double-blind clinical trial; In this way, before obtaining consent, patients are studied but do not know which group they will be in and therefore are blind. Also, the nurse who injects the drug and the researcher who records the patient's symptoms do not know the type of drug and are blind.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

##### Street address

Hezar Jarib St

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-06-22, 1400/04/01

#### Ethics committee reference number

IR.MUI.MED.REC.1399.650

## Health conditions studied

### 1

#### Description of health condition studied

Cataract

#### ICD-10 code

H25

#### ICD-10 code description

Age-related cataract

## Primary outcomes

### 1

#### Description

Heart Rate

#### Timepoint

Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery

#### Method of measurement

ECG monitoring

### 2

#### Description

Sedation quality

#### Timepoint

Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery

## Method of measurement

RSS criteria (Ramsey sedation score)

### 3

#### Description

mean arterial blood pressure

#### Timepoint

Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery

#### Method of measurement

Barometer

### 4

#### Description

Arterial blood oxygen saturation

#### Timepoint

Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery

#### Method of measurement

Pulse oximeter

## Secondary outcomes

### 1

#### Description

Rate of nausea and vomiting

#### Timepoint

Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery

#### Method of measurement

Observation and asking

### 2

#### Description

Duration of anesthesia

#### Timepoint

From the time the first sedation drug is administered until the effects of anesthesia are over

#### Method of measurement

o'clock

### 3

#### Description

Duration of surgery

#### Timepoint

From the time the surgeon starts the cataract until the lens is done

#### Method of measurement

o'clock

## Intervention groups

### 1

#### Description

Intervention group A: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, first receive 300 ml per hour of normal saline for preoperative fluid therapy, then they are given 1 mg per kg body weight of Propofol. (Diateb Company) - Sodium thiopental (Jaber Ibn Hayyan Company) is injected to induce anesthesia. The patient's clinical signs and hemodynamic changes are idolized at regular intervals until the end of recovery.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group B: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, first receive 300 ml per hour of normal saline for preoperative fluid therapy, then they are given 0.3 mg per kg body weight of Propofol. (Diateb Company) - Sodium thiopental (Jaber Ibn Hayyan Company) is injected to induce anesthesia. The patient's clinical signs and hemodynamic changes are idolized at regular intervals until the end of recovery.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Feyz hospital

##### Full name of responsible person

Behzad Nazemoroaya

##### Street address

Qods Square, at the beginning of Modares Street

##### City

Isfahan

##### Province

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##### Postal code

8174675731

##### Phone

+98 31 3445 2031

##### Email

behzad\_nazem@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoo

##### Street address

Hezar Jarib

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research@mui.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Aria

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

**Contact**

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Behzad Nazem roaya

**Position**

Professor assistant of Anesthesia and Intensive care intensive care

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Leyla Rafiei

**Position**

Nurse Anesthetist

**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to

make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available